

ARIZONA DEPARTMENT OF HEALTH SERVICES
PROCEDURES MANUAL
Revised March 2002 (July 1995)

SECTION I. GENERAL ADMINISTRATION

PART 4 HUMAN SUBJECTS REVIEW BOARD POLICY

1. Charge

The Arizona Department of Health Services (ADHS) Human Subjects Review Board (HSRB) is charged to formally review study proposals/protocols and requests for ADHS data from any entity. The HSRB will approve or disapprove such proposals/protocols/requests on the basis of protection of the human subjects' privacy, maintenance of data confidentiality and personal safety from any test, procedure or interview. The HSRB will neither review funding needs nor scientific merit nor make recommendations in these areas, which are the primary responsibility of the submitting organization.

2. Duration

The HSRB shall run concurrent with ADHS or until terminated by the Director, Arizona Department of Health Services (ADHS).

3. Membership

The HSRB shall be comprised of a Chairperson and at least five ADHS members, but no more than one member from any service unit. The exception is the Assistant Registrar and Administrative Counsel are from the Director's Office. The term membership shall be specified by the Director of ADHS.

4. Definitions

Unless otherwise defined, the terms set forth below shall have the following meanings:

- A. "Board" means the ADHS, Human Subjects Review Board (HSRB).
- B. "Department" means the Arizona Department of Health Services (ADHS).
- C. "Human subject" means any individual living or dead about whom

an investigator (whether professional or student) conducting research obtains:

1. data through intervention or interaction with the individual, or
2. identifiable private information.

- D. “Institution@ means any corporation, organization or entity seeking approval for ADHS data use or a research project from the HSRB.
- E. “Interaction@ includes communication or interpersonal contact between investigator and subject.
- F. “Intervention@ includes both physical procedures by which data is gathered and manipulations of the subject or subject-s environment that are performed for research purposes.
- G. “Legally authorized representative@ means an individual or group authorized to present a proposed study protocol or seek data for approval from the HSRB.
- H. “Minimal risk@ means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
- I. “Private information@ includes information about behavior that is obtained in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g. a medical record, birth or death certificate). Private information must be individually identifiable so that the identity of the subject is or may readily be ascertained by the investigator, or associated with the information in order to obtain the information to constitute research involving human subjects.
- J. “Protocol@ means a plan detailing the purpose, methods, and expected results of a specific research study or project.
- K. “Research@ means any systematic investigation, evaluation or study designed to develop or contribute to general knowledge.
- L. “Rules@ shall mean all administrative rules adopted by the ADHS pursuant to the Arizona Administrative Procedures Act, 1986 A.R.S. Title 41, Chapter 6 and the Protection of Human Subjects,

4S CFR 46 revised April 1, 1977 as appropriate.

- M. “Secretary@ means the Secretary of the United States Department of Health and Human Services (HHS) and any officer or employee to whom authority to do business has been delegated.

5. Purpose of the Board

The HSRB is formed pursuant to the provisions of Section 474 of the National Research Act (Public Law 93-348) and Regulations (45 CFR 46.101. et. seq.), to review biomedical and behavioral research involving human subjects conducted, funded, sponsored or using data collected and maintained by the ADHS in order to protect the rights of the human subjects of such research.

6. Nature of Research Requests to be Reviewed

All scientific or behavioral studies or investigations and use of data maintained by the ADHS shall be considered under the purview of the HSRB. This means all new projects developed by ADHS personnel and all outside requests for data but not necessarily projects submitted for funding under state or federal programs unless specifically requested by the funding organization and accepted by the HSRB.

7. Meetings

The Board shall meet at least quarterly at such time and place determined by the Chairperson. The Chairperson may also convene as many meetings as is necessary to conduct reviews of research submitted or conduct any other business coming before the Board.

A. Notice of Board Meetings.

The Chairperson shall determine the time and place of each meeting and provide written notice two calendar weeks before the meeting or as agreed to in the prior meeting.

B. Agenda

An agenda shall be provided and furnished to each Board member along with copies of proposed projects/protocols or data requests to be considered at the meeting.

C. Board Records

The HSRB shall prepare and maintain adequate documentation of all HSRB activities, including the following:

1. Copies of all research proposals reviewed, scientific evaluation, if any, that accompany proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
2. Copies of correspondence related to submission, approval or denial of a project.
3. Minutes of meetings which shall be sufficiently detailed to show attendance at the meetings, actions taken, the vote on these actions, including the number of members voting for, against, and abstaining, the basis for requiring changes in or disapproving research, and a written summary of the discussion of controverted issues and their resolution.
4. Records of continuing review activities.
5. Copies of all correspondence between the HSRB and the research investigators.
6. A current list of all Board members and their addresses.
7. Written procedures for the HSRB as required by regulations adopted by the Secretary.
8. Statements of significant new findings provided to subjects as required by regulations adopted by the Secretary.
9. All records maintained by the HSRB shall be maintained at the Chairperson's office and shall be preserved for at least five years following HSRB action and 10 years in state archives. All records shall be available for inspection and review at reasonable times by authorized representatives of the Secretary or Department.
10. A report of projects received, approved or denied will be sent to each ADHS Assistant Director for information and circulation to their service area.

8. Board Action

Unless otherwise specified, the HSRB shall review research and data requests and take action only at a meeting in which at least two-thirds (4) of the members are present. Research proposals and data requests shall be approved, returned for clarification or disapproved by vote of a majority of the members present.

A. Submission for Review

A request for review of a research proposal or for data for statistical or research purposes shall be submitted to the HSRB in written form. The written proposal shall include the following:

1. A detailed description of the nature of the research to be conducted and the methodology and procedures which the research will utilize. Incomplete requests will be returned for further documentation.
2. A statement of the goals which the research will seek to accomplish.
3. A description of safeguards utilized during the research which are designed to safeguard the rights and welfare of human subjects involved in the research.
4. A description of the records and documentation which will be maintained by the research investigator and the location of such records and how confidentiality and privacy will be maintained.
5. A list of each research investigator along with a description of the investigator's experience and expertise in the area of research proposed to be conducted.
6. A description of how the research investigator intends to monitor results and to report findings.
7. An assurance by the research investigator that the research will be conducted in accordance with applicable law and regulations and Board requirements, and that all material modifications in the research or problems which may develop thereafter in the research shall be immediately submitted to the Board for review and action.
8. A description of how the research investigator will obtain informed consent of the human subjects in accordance with applicable law and rules, along with the written disclosure form by which informed consent will be obtained.
9. Any other information about the proposed research which will facilitate the HSRB's review of the research.
10. All documents other than the protocol should be pertinent and as brief as possible without reducing the clarity of the project's description because the committee's time is limited.
11. A description of how data, especially those items with personal identifiers, will be disposed of or destroyed.

B. Subjects NOT within the Board's Purview.

The HSRB is not responsible for the scientific merit of the proposed research except that poorly prepared research proposals or inappropriate scientific merit in themselves may be considered an unwarranted risk for a human subject or inappropriate for disclosure of confidential records. In general, the methods,

techniques and goals of the research and its approval are the express responsibility of the investigator(s), and the Assistant Director of the Division or Executive Officer of the Institution submitting the request.

1. The HSRB's action cannot be construed as approving, granting or providing funds for the research.
2. Approval by the HSRB does not obligate the ADHS or its subordinate organizational units to necessarily collect, compile, or provide the data requested, but only that the requestor appears capable of managing the data in a confidential manner so as to protect the human subject and the individual's privacy and not cause the ADHS undue criticism.
3. Any release of confidential information should clearly have benefits and scientific merit that outweighs the contemplated invasion of privacy or confidentiality.

C. Confidentiality

The HSRB shall require documentation (a confidentiality statement) of the intent and ability of the researcher to maintain the provided or collected data so as not to violate the privacy of the human subjects, pursuant to A.A. C. R9-19-410.

General conditions for release of information from vital records research, statistical and other uses:

1. Data from vital records, including copies of part of all of such records, may be released to government agencies, hospitals, foundations, schools, social agencies and similar organizations or individuals for statistical or research purposes. All such requests shall clearly identify the requesting agency or individual, state the number of copies needed, explain the objective of the study and contain a statement over the applicant's signature expressing familiarity with the confidentiality aspects of the records and his willingness to abide by the restrictions.
2. In no case shall the researcher either in the published results of his study or in communication with others:
 - a. Identify any individual on a certificate by name or address.
 - b. Contact persons named on a certificate without prior permission from the State Registrar.
 - c. Deliver the information to other persons not

connected with the study.

- d. Use the information in any way so as to violate the privacy of any individual named on a certificate or cause embarrassment to him or his family.

3. Violations will bar the applicant from obtaining further assistance from the Department of Health Services, relating to research of vital records, and will make him liable to such other legal action as may be applicable.

D. Informed Consent.

The HSRB shall require documentation of informed consent by research subjects and shall require that information given to research subjects as a part of informed consent is in accordance with applicable law and specifically in compliance with 45 CFR 46.116 and 46.117, or any other regulations adopted by the Secretary. The HSRB may require additional information be given to research subjects if, in the Board's judgment, the information would meaningfully add to the protection of the rights and welfare of subjects. Research approved by the HSRB pursuant hereto may be subject, in the discretion of the Board, to further appropriate review and approval or disapproval

E. Notification of Board Actions.

The Chairperson of the HSRB will notify the requestor in writing of the HSRB decision to approve, request further clarification, or disapprove the proposed research or data use within five working days of the HSRB meeting. If the HSRB requires clarification or disapproves the proposal or request, it shall include in the written notification a statement of the reasons for its decision and shall give the requestor an opportunity to clarify, revise or otherwise respond in writing. The HSRB may either reaffirm or revise its decision following submission of additional clarifying information.

F. Suspension or Termination of Approval

The HSRB shall have authority to suspend or terminate approval of research not being conducted in accordance with HSRB requirements, has violated the confidentiality requirements, or that has been associated with unexpected serious harm to subjects. Any suspension or termination or approval shall include a statement of the reasons for the HSRB's action and shall be promptly reported to the investigator and the Director, ADHS.

G. Right of Appeal

Any person may petition the Director of the Department for a hearing in accordance with the rules of practice to appeal a rejection, suspension or termination of approval or access to confidential vital records (A.R.S. Title 36, Chapter 3, 36-345, and Title 39, Chapter 1, 39-121.02).

9. Expedited Review of Projects

The Chairperson shall be authorized to review and approve emergency projects requiring the collection of data, biological specimens including blood by finger stick or phlebotomy and other minimal risk procedures in the routine response to emergencies and epidemics where time is of the essence. The HSRB will review the proposal and the Chairperson's decision and provide in the minutes a comment of concurrence or objection. In reviewing projects pursuant to expedited review, the members may exercise all their powers which they, as members, are authorized to exercise except that the project shall not be disapproved. This section applies only to ADHS organizations in the routine performance of their mandated duties and responsibilities.

10. Statement of Ethical Principles

In reviewing the biomedical and behavioral research involving human subjects, the HSRB shall consider and apply the ethical principles set forth in this article X. In general, the ethical principles of the HSRB shall encompass the ethical convictions that individuals be treated as autonomous agents and that individuals with diminished autonomy be entitled to protection. Respect for the autonomy of individuals will require that human subjects involved in research be given the opportunity to choose what shall or shall not happen to them through informed consent. In considering whether a research subject has given informed consent, the HSRB shall consider whether sufficient information has been provided to the human subject. The information shall generally include: the research procedure, the purpose, risk, and anticipated benefit of the research, a statement offering the subject the opportunity to ask questions and to withdraw from the research, and any other information that reasonable persons would wish to know in order to make a decision regarding their care and well-being. With respect to the selection of human subjects for participation in research, the HSRB shall consider whether the research investigator has exhibited fairness in the selection. For selection of subjects, a distinction should be drawn between classes of subjects that ought, and ought not, to participate in a particular kind of research, based upon the ability of members of that class to bear the burden which may be present in the research activity.

11. Criteria for HSRB Approval of Research

To approve research, the HSRB shall determine that all of the following requirements are satisfied:

- A. Risks to subjects are minimized (1) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risks, and (2) whenever appropriate, by using procedures already being performed on the persons for diagnostic or treatment purposes.
- B. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. Social, psychological and physical risks and benefits will be considered. In evaluating risks and benefits, the HSRB shall consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The HSRB shall not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public safety) as among those research risks that fall within the purview of its responsibility.
- C. The ability and methods by which data confidentiality and personal privacy will be maintained are clearly specified.
- D. Informed consent is sought from each prospective subject to the subject's legally authorized representative in accordance with, and to the extent required by, regulations adopted by the Secretary.
- E. Informed consent is appropriately documented in accordance with regulations adopted by the Secretary.
- F. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure safety of subjects.
- G. Adequate procedures exist for continuing review by the HSRB.
- H. Appropriate additional safeguards shall be required by the HSRB in research activities involving subjects likely to be vulnerable to coercion or undue influence, such as subjects with great or severe physical or mental illness, or persons who are economically or educationally disadvantaged.

12. Continuing Review of ADHS Research

The HSRB may conduct continuing review of research approved pursuant hereto, at intervals appropriate to the degree of risk. In approving research activity, the HSRB shall determine a method of verification of research approved by the HSRB.

13. Amendment of Policy

These organizational policies shall not be amended without approval of the Director, ADHS and a majority of the members.